

Iowa Department of Human Services

Terry E. Branstad Governor Kim Reynolds Lt. Governor Charles M. Palmer Director

INFORMATIONAL LETTER NO.1517

DATE: June 8, 2015

TO: Iowa Medicaid Physicians, Dentists, Advanced Registered Nurse

Practitioners, Therapeutically Certified Optometrists, Podiatrists, Pharmacies, Home Health Agencies, Rural Health Clinics, Clinics,

Skilled Nursing Facilities, Intermediate Care Facilities, Nursing Facilities-Mental ILL, Federally Qualified Health Centers (FQHC), Indian Health Service, Maternal Health Centers, Certified Nurse Midwife, Community Mental Health, Family Planning, Residential Care Facilities, ICF/ID State

and Community Based ICF/ID Providers

FROM: Iowa Department of Human Services (DHS), Iowa Medicaid Enterprise (IME)

RE: Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: July 6, 2015

1. Changes to Existing Prior Authorization Criteria- Changes are italicized. See complete prior authorization criteria posted at http://www.iowamedicaidpdl.com/ under the Prior Authorization Criteria tab.

Chronic Pain Syndromes:

A prior authorization is required for pregabalin (Lyrica[®]) and milnacipran (Savella^{$^{\text{M}}$}). These drugs will be considered for their FDA indication(s) and other conditions as listed in the compendia. Payment will be considered under the following conditions:

- 1. A diagnosis of **fibromyalgia** (Lyrica[®] and Savella[™])
 - a. A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following *preferred generic agents*: tricyclic antidepressant or SNRI, **WITH**
- 3. A diagnosis of diabetic peripheral neuropathy (Lyrica®)

A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, *duloxetine* or topical lidocaine.

CNS Stimulants and Atomoxetine:

Prior authorization (PA) is required for CNS stimulants and Atomoxetine for patients 21 years of age or older. Prior to requesting prior authorization for any covered diagnosis, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at https://pmp.iowa.gov/IAPMPWebCenter/. Payment for CNS stimulants and Atomoxetine will be considered under the following conditions:

1. Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized

rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV). Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more *current* environments (social, academic, or occupational). Documentation of a recent clinical visit that confirms the patient continues to require medication to treat the symptoms of ADD/ADHD will be required for renewals or patients newly eligible that are established on medication to treat ADD/ADHD.

- 3. Binge Eating Disorder (Vyvanse only)
 - a. Patient is 18 to 55 years of age; and
 - b. Patient meets the DSM-5 criteria for Binge Eating Disorder; and
 - c. Patient has documentation of moderate to severe BED, as defined by the number of binge eating episodes per week (number of episodes must be reported); and
 - d. Patient has documentation of non-pharmacologic therapies tried, such as cognitive-behavioral therapy or interpersonal therapy, for a recent 3 month period, that did not significantly reduce the number of binge eating episodes; and
 - e. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with topiramate and fluvoxamine
 - f. Prescription is written by a psychiatrist or psychiatric nurse practitioner; and
 - g. Patient has a BMI of 25 to 45; and
 - h. Patient does not have personal or family history of cardiovascular disease; and
 - i. Patient has no history of substance abuse; and
 - i. Is not being prescribed for the treatment of obesity or weight loss;
 and
 - k. Doses above 70mg per day will not be considered.
 - I. Initial requests will be approved for 12 weeks.
 - m. Requests for renewal must include documentation of a change from baseline at week 12 in the number of binge days per week.

DSM-5 Criteria

- Recurrent episodes of binge eating, including eating an abnormally large amount of food in a discrete period of time and has a feeling of lack of control over eating; and
- ii. The binge eating episodes are marked by at least three of the following:
 - 1. Eating more rapidly than normal
 - 2. Eating until feeling uncomfortably full
 - Eating large amounts of food when not feeling physically hungry
 - 4. Eating alone because of embarrassment by the amount of food consumed
 - 5. Feeling disgusted with oneself, depressed, or guilty after overeating; and
- iii. Episodes occur at least 1 day a week for at least 3 months; and

- iv. No regular use of inappropriate compensatory behaviors (e.g. purging, fasting, or excessive exercise) as are seen in bulimia nervosa; and
- v. Does not occur solely during the course of bulimia nervosa or anorexia nervosa.

Moderate to Severe BED

Based on the number of binge eating episodes per week:

Moderate - 4 to 7 Severe – 8 to 13 Extreme – 14 or more

*If a non-preferred long-acting medication is requested, a trial *with* the preferred immediate release and extended release product of the same chemical entity *(methylphenidate class)* or chemically related agent (amphetamine class) is required.

Dextromethorphan/Quinidine (Nuedexta):

Prior authorization is required for Nuedexta®. Payment will be considered under the following conditions:

- 1. Patients must have a diagnosis of pseudobulbar affect (PBA) secondary to a neurological condition.
- 3. Patient has documentation of a current EKG (within the past 3 months) without QT prolongation.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Hepatitis C Agents:

Prior authorization is required for *hepatitis C treatments*. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

- Patient is 18 years of age or older and has a diagnosis of chronic hepatitis
 C: and
- 2. Patient has had testing for hepatitis C virus (HCV) genotype; and
- 3. Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and
- 4. Viral load will be submitted by prescriber 12 weeks after the completion of therapy; and
- 5. Patient has advanced liver disease corresponding to a Metavir score of 3 or greater fibrosis as confirmed by one of the following:
 - Liver biopsy confirming a Metavir score ≥ F3; or
 - Transient elastography (FibroScan) score ≥ 9.5kPa; or
 - FibroSURE (FibroTest) score ≥ 0.58; or
 - APRI score > 1.5; or
 - Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension); or
 - Physical findings or clinical evidence consistent with cirrhosis; or
 - Patients at highest risk for severe complications: organ transplant,

type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis), proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis.

- 6. Patient's prior treatment history is provided (treatment naïve or *treatment experienced*; and
- 7. If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and
- 8. Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test; and
- 9. Patient does not have severe renal impairment (creatinine clearance <30ml/min) or end stage renal disease requiring hemodialysis; and
- 10. HCV treatment is prescribed by a digestive disease, liver disease, or infectious disease provider practice; and.
- 11. For patients on a regimen containing ribavirin, the following must be documented on the PA form:
 - a) Patient is not a pregnant female or a male with a pregnant female partner; and
 - b) Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and
 - c) Monthly pregnancy tests will be performed during treatment; and
- 12. Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication.
- 13. Documentation is provided for patient's who are ineligible to receive interferon or ribavirin.
- 14. Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved.
- 15. If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on established length of therapy for the particular treatment (defined below).
- 16. Lost or stolen medication replacement requests will not be authorized.
- 17. The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.

Sedative/Hypnotics Non-Benzodiazepines:

Preferred agents are available without prior authorization (PA). Requests for doses above the manufacturer recommended dose will not be considered. Prior authorization is required for all non-preferred non-benzodiazepine sedative/hypnotics. Payment for non-preferred non-benzodiazepine sedative/hypnotics will be authorized only for cases in which there is documentation of previous trials and therapy failures with, at a minimum, three (3) preferred agents. Payment for non-preferred non-benzodiazepine sedative/hypnotics will be considered when the following criteria are met:

- 1. A diagnosis of insomnia; and
- 2. Medications with a side effect of insomnia (i.e. stimulants) are decreased in dose, changed to a short acting product, and/or discontinued; *and*
- 3. Enforcement of good sleep hygiene is documented; and
- 4. All medical, neurological, and psychiatric disease states causing chronic insomnia are being adequately treated with appropriate medication at therapeutic doses.
- 5. In addition to the above criteria, requests for suvorexant (Belsomra) will require documentation of a trial and therapy failure with at least one non-preferred agent, other than suvorexant, prior to consideration of coverage.
- 6. Non-preferred alternative delivery systems will only be considered for cases in which the use of the alternative delivery system is medically necessary and there is a previous trial and therapy failure with a preferred alternative delivery system if available.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

2. Point of Sale Billing Issues:

a. ProDUR Quantity Limits: The following quantity limit edits will be implemented effective *July 6, 2015*. A comprehensive list of all quantity limit edits appears on our website, www.iowamedicaidpdl.com under the heading, "Quantity Limits".

Drug Product	Quantity	Days Supply
Eurax	60 gms	30
Ritalin LA 60mg	30	30

b. Gender Edit for Prenatal Vitamins: Effective **July 6, 2015** prenatal vitamins will only be payable for female members. Claims for prenatal vitamins for male members will deny with a rejection message of *70 PRODUCT/SERVICE NOT COVERED – Gender specific drug.*

3. Preferred Brand Name Drugs on the PDL-Pharmacy Clarification

When a status change occurs for a previously preferred brand name drug to non-preferred status, up to a *minimum* of 30 days transition period is given to pharmacies to help utilize existing brand name product in stock in an effort to decrease a pharmacy's remaining brand name drug inventory (see PDL comment section regarding transition periods exceeding 30 days). If additional stock remains beyond this time period, pharmacies may call the POS Helpdesk at 877-463-7671 or 515-256-4608 (local) to request an override for the non-preferred brand name drug with a recent status change.

4. DUR Update: The latest issue of the Drug Utilization Review (DUR) Digest is located at the lowa DUR website, www.iadur.org under the "Newsletters" link.

We encourage providers to go to the website at www.iowamedicaidpdl.com to view all recent changes to the PDL. If you have questions, please contact the Pharmacy Prior Authorization Helpdesk at 877-776-1567 or 515-256-4607 (local in Des Moines) or email info@iowamedicaidpdl.com.